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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,779	03/08/2001	James E. Hildreth	JHU1710-3	9936

7590 04/04/2002

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/04/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,779	HILDRETH, JAMES E.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Objections

2. Claims 3, 20, and 34 are objected to because of the following informalities: Misspelling of the term "herpesvirus". A space should be used to separate the two words. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "composition of claim 27" in the first line of claim 39. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claims 1-8 are drawn to a method of reducing the risk of transmission of a sexually transmitted pathogen comprising contacting the pathogen or cells susceptible to infection with a β -cyclodextrin.

Bergeron discloses a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The formulation acts as a

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physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Bergeron does not disclose the use of a β -cyclodextrin.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β -cyclodextrin since β -cyclodextrins are widely used in the pharmaceutical industry to solubilize and stabilize active agents. Optimization of the experimental conditions would provide the motivation for doing so.

8. Claims 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claims 9-22 are drawn to a method of reducing the risk of a subject becoming infected with a sexually transmitted pathogen comprising contacting the pathogen or cells susceptible to infection with a composition comprising a β -cyclodextrin.

Bergeron discloses a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The formulation acts as a

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physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Bergeron does not disclose the use of a 2-hydroxypropyl β -cyclodextrin. Bergeron does not disclose the composition being formulated into a suppository, film, vaginal disk, or condom.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a 2-hydroxypropyl β -cyclodextrin since 2-hydroxypropyl β -cyclodextrin is widely used in the pharmaceutical industry to solubilize and stabilize active agents. Optimization of the experimental conditions would provide the motivation for doing so. It would have also been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition disclosed by Bergeron into a condom or suppository since they are well known in the art for the prevention of sexually transmitted diseases. One would have been motivated to do so in order to provide the formulation in an already known and widely used form.

9. Claims 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claims 23-36 are drawn to a method of reducing the risk of transmission of a sexually transmitted disease by a subject infected with a sexually transmitted pathogen comprising contacting the pathogen or cells susceptible to infection with a composition comprising a β -cyclodextrin.

Bergeron discloses a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Bergeron does not disclose the use of a 2-hydroxypropyl β -cyclodextrin. Bergeron does not disclose the composition being formulated into a suppository, film, vaginal disk, or condom.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a 2-hydroxypropyl- β -cyclodextrin since 2-hydroxypropyl β -cyclodextrin

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is widely used in the pharmaceutical industry to solubilize and stabilize active agents. Optimization of the experimental conditions would provide the motivation for doing so. It would have also been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition disclosed by Bergeron into a condom or suppository since they are well known in the art for the prevention of sexually transmitted diseases. One would have been motivated to do so in order to provide the formulation in an already known and widely used form.

10. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claims 37-39 are drawn to a composition comprising a β -cyclodextrin and an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant, and a combination thereof.

Bergeron discloses a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The inhibitors are preferably encapsulated in a

liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used in conjunction with the invention disclosed by Bergeron include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). Bergeron does not disclose the use of a β -cyclodextrin.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β -cyclodextrin since β -cyclodextrins are widely used in the pharmaceutical industry to solubilize and stabilize active agents. Optimization of the experimental conditions would provide the motivation for doing so.

11. Claims 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Claims 40-45 are drawn to a composition comprising a β -cyclodextrin and a solid substrate.

Bergeron discloses a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The inhibitors are preferably encapsulated in a

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liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used in conjunction with the invention disclosed by Bergeron include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). Bergeron does not disclose the use of a β -cyclodextrin. Bergeron does not disclose the composition being formulated into a condom, diaphragm, vaginal disk, vaginal film, glove, sponge, or tampon.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β -cyclodextrin since β -cyclodextrins are widely used in the pharmaceutical industry to solubilize and stabilize active agents. Optimization of the experimental conditions would provide the motivation for doing so. It would have also been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition disclosed by Bergeron into a condom, diaphragm, glove, sponge, or tampon since they are well known in the art for the prevention of sexually transmitted diseases. One would have been motivated to do so in order to provide the formulation in an already known and widely used form.

Conclusion

12. Claims 1-45 are pending. Claims 1-45 are rejected. No claims are allowed.

Contacts

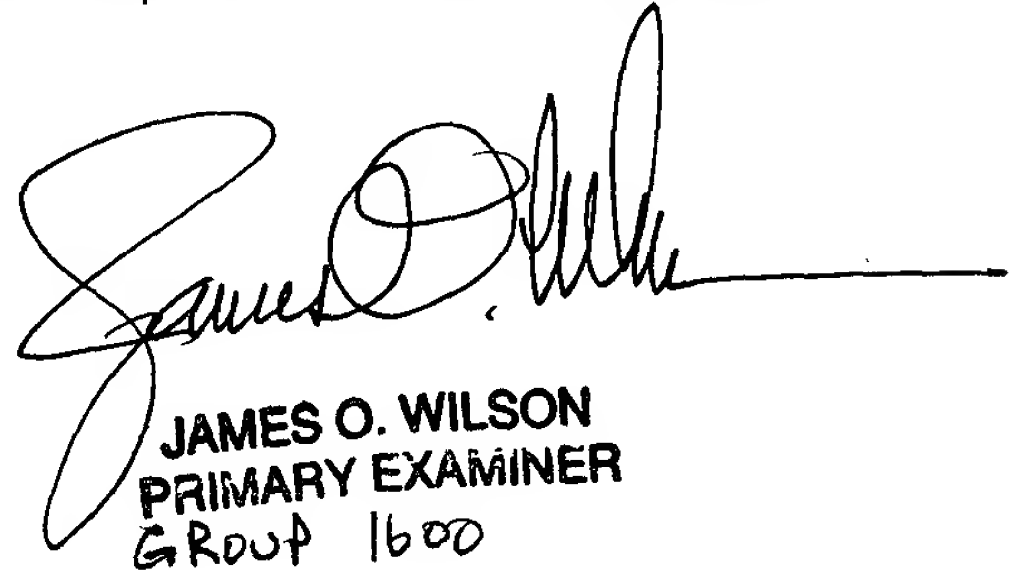
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis
Examiner
Art Unit 1623

ptl
March 27, 2002



JAMES O. WILSON
PRIMARY EXAMINER
Group 1600